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| EXAMINER | |
|---|---|
| PURDY, KYLE A | |

| ART UNIT | PAPER NUMBER |
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| 1611 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/554,299 | MAXWELL, KAMERON W. | |
| | Examiner | Art Unit | |
| | Kyle Purdy | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15,32-34 and 36-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15, 32-34 and 36-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of Application*

1. The Examiner acknowledges receipt of the amendments filed on 04/29/2009 wherein claims 1, 6, 7, 9, 32, 34, 37-40 and 42 have been amended and claims 35-43 have been cancelled.

2. Claims 1-15, 32-34 and 36-47 are presented for examination on the merits. The following rejections are made.

### *Response to Applicants' Arguments*

3. Applicants arguments filed 04/29/2009 regarding the rejection of claim 35 made by the Examiner under obviousness-type double patenting over copending application 10/675225 have been fully considered and they are found persuasive. This rejection has been overcome by cancellation of the claims.

4. Applicants arguments filed 04/29/2009 regarding the rejection of claim 35 made by the Examiner under obviousness 35 USC 103(a) over Mitchell (US 5462946) in view of Stern (2002) and Herfindal (1992) have been fully considered and they are found persuasive. This claim has been cancelled.

5. Applicants arguments filed 04/29/2009 regarding the rejection of claims 1-15 and 32-47 made by the Examiner under 35 USC 112, first paragraph (scope of enablement) have been fully considered and they are found persuasive. This rejection has been withdrawn insofar as the instant claims are currently limited to the elected species of 4-hydroxy-2,2-6,6-tetramethylpiperidien-1-oxyl which are currently enabled. However, cancellation of this compound and examination of another nitroxide may result in reinstatement of this rejection. Note, claim 35 has been cancelled.

6. Applicants arguments filed 04/29/2009 regarding the rejection of claims 1-15 and 32-47 made by the Examiner under 35 USC 112, second paragraph (indefiniteness) have been fully considered and they are found persuasive. This rejection ahs been overcome by amendment to the claim.

7. Applicants arguments filed 04/29/2009 regarding the rejection of claims 1-15, 32-34 and 36-47 made by the Examiner under obviousness-type double patenting over copending application 10/675225 have been fully considered but they are not found persuasive.

8. The rejection of claims 1-15, 32-34 and 36-47 made by the examiner under obviousness-type double patenting is **MAINTAINED** for the reasons of record in the office action mailed on 10/29/2009.

9. In regards to the double patenting rejection, Applicant asserts the following:

**A)** The disclosure of the secondary reference may not be used to establish obviousness type double patenting.

In response to A, this is not found persuasive. MPEP 814 also states that in determining if an obviousness-type double patenting rejection is to be made, it is necessary to 1) determine the scope and content of a patent claim relative to a claim in the application at issue; 2) Determine the differences between the scope and content of the patent claim of 1) and the claims in the application at issue; 3) Determine the level of ordinary skill in the pertinent art; and 4) evaluate any objective indicia of nonobviousness. Moreover, upon determining the differences between the conflicting claims, the reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the other defined invention. Determining obviousness therefore may require providing a

secondary reference (i.e. Stern) for illustrating the level of ordinary skill in the art. It's also pointed out that while the MPEP states that "when considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art." However, this does not mean that one is precluded form all use of patent disclosure. Consistent with the MPEP citation above, applicant is correct in that the disclosure of the patent or copending application which serves as the basis for the obviousness-type double patenting rejection cannot be relied upon as prior art, it is noted that the examiner may properly rely upon the teachings of the prior art to ascertain whether the instantly claimed invention is an obvious variant to a person of ordinary skill in the art. This part of the obviousness-type double patenting analysis is analogous to an obviousness analysis under 35 U.S.C. §103, except that the conflicting patent or copending application is not considered prior art. *See In re Longi*, 759 F.2d 887, 892 n.4 [225 USPQ 645] (Fed. Cir. 1985) ("[A] double patenting of the obviousness-type rejection is analogous to [a failure to meet] the non-obviousness requirement of 35 U.S.C. §103, except that the patent principally underlying the double patenting rejection is not considered prior art." (quotation marks omitted)). Thus, while the obviousness-typ double patenting analysis is limited to the claims of the copending application of the instant rejection, Stern is properly relied upon in determining the obviousness of the instantly claimed invention.

10. Applicants arguments filed 04/29/2009 regarding the rejection of claims 1-15, 32-34 and 36-47 made by the Examiner under obviousness 35 USC 103(a) over Mitchell in view of Stern and Herfindal have been fully considered but they are not found persuasive.

11. The rejection of claims 1-15, 32-34 and 36-47 made by the examiner under 35 USC 103(a) is **MAINTAINED** for the reasons of record in the office action mailed on 10/29/2009.

12. In regards to the obviousness rejection, Applicant asserts the following:

**B)** The Office has not established that a predictable result would occur by administering TEMPOL "prior to the onset of ischemia";

**C)** the term 'protectant' in Mitchell means to protect from death after injury, rather than a protectant against the injury itself; and

**D)** the Office has not established a prima facie obviousness case for the ischemia arising from a medical procedure for the treatment of hemorrhage, an aneurysm, surgery and endovascular procedures.

13. In response to B, the Examiner has established such a case. Mitchell establishes that nitroxide compounds such as TEMPOL are useful because they ameliorate the deleterious effects of toxic oxygen-related species in living organisms and that the compounds can be used in a variety of conditions which have such symptoms. An exemplified condition is reperfusion injury, due to various causes such as surgery. TEMPOL is to be administered in a way that would prevent the manifestation of oxidative stress (i.e. ischemia). Moreover, Mitchell suggests that the method of administering the composition be to mammal susceptible to oxidative stress wherein the stress may be due to reperfusion injury (see column 5, lines 25-35). Mitchell clearly suggests using the TEMPOL prior to the onset of ischemia. Thus, if an ordinary person were to heed the suggestion of Mitchell, the result would have been the reduction in ischemia. Such a method and result would have been the product of ordinary skill and common sense.

14. In response to C, the relevance of this argument is not clear. Mitchell teaches that TEMPOL is useful as a 'reperfusion injury protectant'. Whatever the meaning of 'protectant' is it is irrelevant because it's understood that treatment of reperfusion injury with TEMPOL would result in a reduction of oxidative damage due to the insult.

15. In response to D, Mitchell teaches TEMPOL is a reperfusion injury protectant useful for treating myocardial infarction and stroke as well as organ transplants (i.e. surgery). It's common knowledge that hemorrhage and aneurysm are both variations of stroke, and that endovascular procedures are commonly performed on stroke victims. This is evidenced by the American Stroke Association, see http://www.strokeassociation.org/presenter.jhtml?identifier=1014 (.PDF provided). Any ordinary person would have been able to know that since the compounds can be used to reduce reperfusion injury due to stroke, they would have similarly been useful for treating of reperfusion injury due to treatment of hemorrhage and aneurysm.

## Maintained Rejections, of Record

### *Nonstatutory Obviousness-Type Double-Patenting*

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

*Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

17. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

18. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. **Claims 1-15, 32-34 and 36-47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-17, and 19-25 of copending U.S. Patent Application No. 10/675,225, in view of Stern Stern S. (Circulation. 2002;106:1906-1908).**

20. In particular, reference claim 16 recites "[a] method of treating a patient, comprising topically applying a sufficient amount of a nitroxide radioprotector to prevent or treat harmful side effects caused by radiotherapy, wherein the nitroxide radioprotector is in solution in a solvent, and the solution is in the form of a low-residue gel or a low-residue thickened liquid." Reference claim 17, for example, recites the identical compound as recited in instant claim 2. Unlike the instant claims, the reference claims do not recite the step of identifying a human

patient that is susceptible to ischemia. It is the examiner's position the instant claim term "human patient susceptible to ischemia" reasonably encompasses all human patients, including the reference patient population. Further, the reference step of topically applying a sufficient amount of a nitroxide radioprotector (e.g. 4-hydroxy-2,2-6,6-tetramethylpiperidien-1-oxyl; see reference claims 16-17) to prevent or treat harmful side effects caused by radiotherapy is capable of performing the intended function i.e. preventing a harmful effect of ischemia in a human patient prior to the onset of ischemia. The discussion of Stern in connection with the rejection under 103(a) is incorporated by reference. Despite the difference between the reference claims and the instant claims, it would have been obvious to a person of skill in the art at the time the invention was made to first identify a high-risk male human patient with ischemic heart disease (IHD) prior to scheduling said high-risk male human patient to a medical procedure (e.g. exercise testing) as taught by Stern, followed by the reference method of treatment comprising administering 4-hydroxy-2,2,6,6- tetramethylpiperidine-1-oxyl (TEMPOL = applicant's elected nitroxide species) in order to control ischemia. One would have been motivated to first identify a high-risk male human patient with ischemic heart disease (IHD) and schedule said high-risk male human patient to a medical procedure (e.g. exercise testing) in order to accurately diagnose IHD because Stern suggest that medical procedures (e.g. exercise testing) can identify high-risk men, even asymptomatic men, with IHD (e.g. myocardial infarction). Thus, it would have been obvious to a person of skill in the art at the time the invention was made to create the instant claimed invention with reasonable predictability.

21. This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

***Claim Rejections – 35 USC 103(a)***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

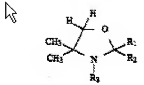
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

23. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

24. **Claims 1-15, 32-34 and 36-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell et al. (US Patent 5,462,946; of record), in view of Stern S. (Circulation. 2002;106:1906-1908), evidenced by Herfindal et al. (Clinical Pharmacy and Therapeutics. 1992, 677-709; of record).**

25. Mitchell teach intravenous administration of compounds having the below formula, including 2,2,6,6-tetramethylpiperidine-1-oxyl (also known as TEMPO) and the elected compound, 4-hydroxy-2,2,6,6-tetramethylpiperidine-1-oxyl (also know as TEMPOL), for use as a protectant against oxidative stress in treating various conditions associated with oxidative stress such as reperfusion injury, strokes, myocardial infraction, wherein said compounds are

administered intravenously in an amount of about 0.01 to about 300 mg/kg/day (see abstract; col. 2, 62 to col. 3, line 10; and col. 4, line 43 to col. 5, line 58):



wherein $R_1$ is $-CH_3$; $R_2$ is $-C_2H_5$, $-C_3H_7$, $-C_4H_9$, $-C_5H_{11}$, $-C_6H_{13}$, $-CH_2-CH(CH_3)_2$, $-CHCH_3C_2H_5$, or $-(CH_2)_7-CH_3$, or wherein $R_1$ and $R_2$ together form spirocyclopentane, spirocyclohexane, spirocycloheptane, spirocyclooctane, 3-cholestane, or norbornane, $R_3$ is $-O$, or $-OH$, or a physiologically acceptable salt thereof, and a pharmaceutically acceptable carrier, as antioxidants capable of protecting cells, tissues, organs, and whole organisms against the deleterious effects of harmful oxygen-derived species generated during oxidative stress.

26. However, Mitchell et al. is silent regarding the instant step of identifying a human patient that is susceptible to ischemia.

27. Stern is added to show the risk associated with ischemia. Stern et al. that exercise testing can identify high- risk men, even if asymptomatic, who could benefit from risk reduction and preventive measures (page 1907, especially col. 1, first full para.). Stern teaches that myocardial defects detected on stress thallium testing or ventricular dysfunction seen on stress examinations are accepted as evidence for transient ischemia, despite the lack of both accompanying ECG alterations and chest pain (page 1907, col. 1, second full para.). Stern teaches that because myocardial infarction (MI) may be silent, awareness is called for when sudden unexplained cardiac symptoms appear (page 1907, col. 2, conclusion section).

28. Herfindal is added as an evidentiary reference only to show that ischemia means a lack of oxygen secondary to reduced perfusion. Herfindal teach that ischemia refers to a lack of oxygen

secondary to reduced perfusion (Herfindal et al. (eds.). Clinical Pharmacy and Therapeutics. 1992, pages 677-707, and 709; see page 677, first para). Herfindal also teach that myocardial ischemia is caused by an imbalance between oxygen supply and demand usually as a result of atherosclerosis in the large epicardial coronary arteries; it may also occur as a consequence of either focal or generalized vasospasm of the major coronary arteries (page 677, first para.).

29. Therefore, it would have been obvious to a person of skill in the art at the time the invention was made to identify a person at risk of ischemia as taught by Stern prior to treating a patient with reperfusion injury (e.g. MI) by administering 4-hydroxy-2,2,6,6-tetramethylpiperidine-1-oxyl (TEMPOL = applicant's elected nitroxide species) as taught by Mitchell. One would have been motivated to identify a patient susceptible to ischemia and then administer 4-hydroxy-2,2,6,6- tetramethylpiperidine-1-oxyl because Stern suggests that testing can identify high risk men, even if asymptomatic, who could benefit from risk reduction and preventive measures. Besides, it is the examiner's position that it is routine in the art to first diagnose (= identify) a patient with ischemia (e.g. myocardial infarction) prior to administering treatment for said myocardial infarction i.e. diagnostic tests by definition are performed routinely in the medical art to diagnose patients with specific conditions (= functional equivalent of identifying a patient with a specific condition e.g. ischemia). One would have expected to successfully identify a patient susceptible for ischemia, then treating said patient by administering 4-hydroxy-2,2,6,6- tetramethylpiperidine-1-oxyl (TEMPOL = applicant's elected nitroxide species) because Mitchell teach 4-hydroxy-2,2,6,6- tetramethylpiperidine-1-oxyl (TEMPOL) for use as a protectant against oxidative stress in treating various conditions associated with oxidative stress such as reperfusion injury (e.g. MI) and strokes, wherein said

compounds are administered intravenously in an amount of about 0.01 to about 300 mg/kg/day (see abstract; col. 2, 62 to col. 3, line 10; and col. 4, line 43 to col. 5, line 58) and myocardial infarction is an oxidative stress as evidenced by the teaching of Herfindal and the dose taught by the prior art overlaps with the dose of Tempol disclosed in the instant application. Further, one would have also expected to successfully treat any patient that is identified as being susceptible to ischemia, including patients wherein the susceptibility arises from a medical procedure associated with a significant ischemic risk (e.g. treatment of hemorrhage, aneurysm, and endovascular procedure), as Mitchell provides a general teaching of ischemia and therefore one of skill in the art would reasonably have expected to achieve similar end treatment results (i.e. reducing a harmful effect of ischemia) by administering 4-hydroxy-2,2,6,6-tetramethylpiperidine-1-oxyl (TEMPOL = applicant's elected nitroxide species) to any patient identified as being susceptible to ischemia from others etiologic causes (e.g. ischemia associated with treatment of hemorrhage/ aneurysm/ and endovascular procedure).

30. It is noted that it is the examiner's position that it would have been within the skill and knowledge of an artisan skilled in the art to identify a patient susceptible of ischemia associated with medical procedures, including medical procedures for treating hemorrhage, aneurysm, as well as ischemia associated with endovascular procedures, without resorting to undue experimentation in the absence of evidence to show the contrary.

31. It is also noted that the term 4-hydroxy-2,2,6,6- tetramethylpiperidine-1-oxyl (TEMPOL = applicant's elected nitroxide species) as taught by Mitchell et al. reads on the nitroxide component recited in claims 1, 2, 10, 32, 33, 34, 35, 42, and 43.

32. It is further note that the dose of 4-hydroxy-2,2,6,6- tetramethylpiperidine-1-oxyl (TEMPOL = applicant's elected nitroxide species) of 0.1 to 300 mg/kg/day taught by Mitchell for use as a protectant against oxidative stress in treating various conditions associated with oxidative stress such as reperfusion injury, myocardial infarction and strokes overlaps with the dose of TEMPOL exemplified in the instant (i.e. 1-300 mg/kg; see page 12, para. 0058).

33. In addition, it is the examiner's position that the sequence of first identifying a patient with ischemia, followed by administering TEMPOL, or alternatively, first administering TEMPOL, then identifying a patient with ischemia is within the skill of artisan skilled in the art (see claim 42).

***Conclusion***

34. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

35. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/*
*Examiner, Art Unit 1611*
*November 23, 2009*

/David J Blanchard/
Primary Examiner, Art Unit 1643